

Remarks

The claims were amended in accordance with the amendments above. The amendments to the claims are being made merely to clarify the invention. All of the amendments are fully supported by the specification, claims, and figures as originally filed. No new matter is believed or intended to be involved.

§112 Rejections

In the Office Action dated 07/08/2009, claims 1, 3, 4, 6-9, 11-24, 27-28, and 32-47 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular, the Office stated that the limitation in claim 1 reciting “a reservoir having a volume of active agent” lacked adequate support in the original disclosure. According to the Office, the disclosure was limited to the reservoir being filled with cells. The Office further stated that the limitation in claim 1 reciting “the core is in fluid communication with the reservoir” lacked adequate support in the original disclosure.

Whenever the issue of written description support under §112 arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). See also MPEP 2163.02. It is also well settled that an Applicant may rely on the originally filed claims for written description support under §112. See *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980) (original claims constitute their own description); accord *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); accord *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). Furthermore, there is no “in haec verba requirement” under §112 - an Applicant is not limited to the exact wording of the specification when selecting words for the claims. See MPEP 2163. In view of the foregoing, and for at least the reasons set forth below, Applicant submits that the amended claims find more than adequate written description support by the original disclosure in accordance with §112.

Applicant notes that original claim 28 recited “the reservoir contains active agent.” Applicant submits that this alone would provide adequate support under §112 for a limitation in

claim 1 reciting “a reservoir having a volume of active agent.” Nevertheless, Applicant has amended claim 1 to recite “the reservoir contains active agent.” This part of claim 1 thus parrots language from original claim 28 verbatim. Furthermore, paragraph [0097] of the original disclosure clearly demonstrates that the inventors contemplated that various substances could be provided within the reservoir, such that the inventors’ contemplation was not limited to just cells *per se*. The Office cannot credibly take or sustainably maintain a position that the recitation of “the reservoir contains active agent” in amended claim 1 lacks adequate support under §112. Applicant therefore respectfully requests that this part of the §112 rejection be withdrawn.

Applicant further notes how FIGS. 15-16 and paragraph [0097] of the original disclosure show and describe openings between the biomaterial and the reservoir, allowing the substance in the reservoir to contact the biomaterial. Paragraph [0097] also provides the example of “serum” being the substance within the reservoir. Applicant submits that one of ordinary skill in the art would immediately recognize that this combination of teachings clearly shows that the inventors were in possession of the core of the biomaterial being in fluid communication with the reservoir as recited in the previous version of claim 1. Nevertheless, claim 1 has been amended to simply state that the biomaterial is “in communication with the reservoir.” Given the above-noted teachings of FIGS. 15-16 and paragraph [0097] in particular, Applicant maintains that one of ordinary skill in the art would immediately recognize that this combination of teachings clearly shows that the inventors were in possession of the biomaterial being in communication with the reservoir. In other words, this part of amended claim 1 clearly has adequate written description support under §112. Applicant therefore respectfully requests that this part of the §112 rejection also be withdrawn.

### Conclusion

Applicant expressly reserves all rights and arguments with respect to distinctions not explicitly noted herein. In addition, to the extent that the amendments constitute a narrowing of the claims, such narrowing of the claims should not be construed as an admission as to the merits of the prior rejections. Indeed, Applicant traverses the rejections and preserves all rights and arguments. To the extent that any particular statement or argument by the Office in the pending Office Action has not been explicitly addressed herein, the same should not be construed as an

acquiescence or admission by the Applicant that such statements or arguments by the Office are accurate or proper.

Based on the foregoing, all pending claims are in a condition for allowance. Accordingly, Applicant respectfully requests reconsideration and an early notice of allowance. Should the Examiner wish to discuss the amendments or arguments made herein, Applicant invites the Examiner to contact the undersigned at (513) 369-4811 or via e-mail at [aulmer@fbtlaw.com](mailto:aulmer@fbtlaw.com).

The Commissioner for Patents is hereby authorized to charge any deficiency, including any fees required for an extension of time not already paid for or any other required fees not already paid for, or to credit any overpayment of fees, to Frost Brown Todd LLC Deposit Account No. 06-2226.

Respectfully Submitted,



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